

IN THE CLAIMS:

Please add new claims 113 and 114 as follows:

1. (original) A fastener for use in a mammalian body, comprising:  
a first member;  
a second member,  
the first and second members having first and second ends; and  
a connecting member fixed to each of the first and second members  
intermediate the first and second ends and extending between the first and second  
members,  
the first and second members being separated by the connecting member, and  
one of the first and second members having a longitudinal axis and a through  
channel along the axis arranged to be slidably received on a tissue piercing  
deployment wire.

2. (original) The fastener of claim 1 wherein one end of the one of the first and  
second members further includes a pointed tip.

3. (original) The fastener of claim 2 wherein the connecting member is flexible  
permitting another one of the first and second members to be next to the one of the first  
and second members when the one of the first and second members is on the tissue  
piercing deployment wire.

4. (original) The fastener of claim 2 wherein the pointed tip is conical.

5. (original) The fastener of claim 2 wherein the pointed tip comprises a  
sectioned portion.

6. (original) The fastener of claim 2 wherein the pointed tip is a dilation tip.

7. (original) The fastener of claim 1 wherein the through channel comprises a through bore.

8. (original) The fastener of claim 1 wherein both the first and second members include a longitudinal axis and a through channel along each respective axis.

9. (original) The fastener of claim 8 wherein one end of both the first and second members includes a pointed tip.

10. (original) The fastener of claim 9 wherein the pointed tips point in opposite directions.

11. (original) The fastener of claim 8 wherein the through channels are through bores.

12. (original) The fastener of claim 8 wherein the through channels are arranged to be slidably received by the tissue piercing deployment wire and wherein the connecting member is flexible permitting the first and second members to be in line with each other on the tissue piercing deployment wire.

13. (original) The fastener of claim 1 wherein the fastener is at least partially radio opaque.

14. (original) The fastener of claim 1 wherein the length of the connecting member between the first and second members is adjustable.

15. (original) The fastener of claim 1 wherein the connecting member is formed of elastic material.

16. (original) The fastener of claim 1 wherein the first member, the second member, and the connecting member are all formed of plastic material.

17. (original) The fastener of claim 16 wherein the first member, the second member, and the connecting member are all formed in one piece.

18. (original) The fastener of claim 17 wherein one end of the one of the first and second members further includes a pointed tip.

19. (original) The fastener of claim 18 wherein the pointed tip comprises a truncated cone.

20. (original) The fastener of claim 18 wherein the through channel comprises a through bore.

21. (original) The fastener of claim 17 wherein both the first and second members include a longitudinal axis and a through channel along each respective axis.

22. (original) The fastener of claim 21 wherein one end of both the first and second members includes a pointed tip.

23. (original) The fastener of claim 22 wherein the pointed tips point in opposite directions.

24. (original) The fastener of claim 16 wherein the connecting member is formed of plastic elastic material.

25. (original) The fastener of claim 16 wherein the connecting member is formed of a plastic, permanently deformable material.

26. (original) The fastener of claim 16 wherein the plastic material includes a color pigment contrasting with body tissue color to enable visualization of the fastener with an endoscope.

27. (original) The fastener of claim 17 wherein the connecting member has a vertical dimension and a horizontal dimension transverse to the vertical dimension, and wherein the horizontal dimension is substantially less than the vertical dimension rendering the connecting member readily bendable in a horizontal plane.

28. (original) The fastener of claim 17 wherein at least one of the first and second members includes a plurality of longitudinally spaced vertical slots rendering the at least one of the first and second members flexible in a direction opposite the slots but stiff in a direction of the slots.

29. (original) The fastener of claim 1 further comprising a plurality of connecting members extending between the first and second members.

30. (original) The fastener of claim 1 wherein the first and second members and the connecting member are formed of different materials.

31. (original) The fastener of claim 1 wherein the first and second members and the connecting member have different textures.

32. (original) The fastener of claim 1 wherein the first member, the second member, and the connecting member are integrally formed from a same tubular member stock.

33. (original) The fastener of claim 32 wherein both the first and second members include a through channel for being slidably received in line on the tissue piercing deployment wire.

34. (original) The fastener of claim 32 wherein the fastener is formed of metal.

35. (original) The fastener of claim 33 wherein the fastener is formed of a shape memory material and wherein the first and second members are self-deployable.

36. (original) The fastener of claim 35 wherein the fastener is formed of nitinol.

37. (original) The fastener of claim 33 wherein at least one of the first and second members is self-deployable while on the tissue piercing deployment wire.

38. (original) The fastener of claim 33 wherein at least one of the first and second members is self-deployable upon removal from the tissue piercing deployment wire.

39. (original) The fastener of claim 38 wherein the at least one of the first and second members includes a restrictor that provides a controlled resistance to movement between the fastener and the tissue piercing deployment wire.

40. (original) The fastener of claim 39 wherein the restrictor comprises a crimp.

41. (original) The fastener of claim 32 wherein the connecting member comprises a strip of the tubular member formed by a pair of longitudinal substantially parallel, substantially coextensive cuts within the tubular member and the first and second members are formed by a substantially transverse circumferential cut between the substantially parallel coextensive cuts.

42. (original) The fastener of claim 41 wherein the tubular member has first and second opposed ends and wherein the substantially parallel substantially coextensive cuts begin spaced from the first end and terminate spaced from the second ends, and wherein the first and second members are tubular member sections between the circumferential cut and the tubular member first and second ends.

43. (original) The fastener of claim 42 further comprising an elongated notch extending from one of the ends of the tubular member, substantially diametrically opposite and juxtaposed to a portion of the connecting member strip.

44. (original) The fastener of claim 1 wherein the fastener is formed of a shape memory material.

45. (original) The fastener of claim 44 wherein the metal material is a shape memory material.

46. (original) The fastener of claim 45 wherein the shape memory material is Nitinol.

47. (original) A fastener assembly for use in a mammalian body, comprising:  
a fastener including a first member, a second member, wherein the first and second members have first and second ends, and a connecting member fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members, wherein the first and second members are separated by the connecting member, and wherein one of the first and second members has a longitudinal axis and a through channel along the axis;

a deployment wire that slidably receives the through channel of the one of the first and second members and pierces into the tissue; and

a pusher that pushes the one of first and second members into the tissue while on the deployment wire.

48. (original) The assembly of claim 47 wherein the pusher is also arranged to be slidably received on the deployment wire.

49. (original) The assembly of claim 47 wherein the connecting member of the fastener is flexible, and wherein the assembly further comprises a guide tube extending over the deployment wire and the fastener, the other one of the first and second

members being disposed next to the one of the first and second members within the guide tube.

50. (original) The assembly of claim 47 wherein the first and second members are arranged to be side by side when the one of the first and second members is slidingly received on the deployment wire.

51. (original) The assembly of claim 47 wherein one end of the one of the first and second members of the fastener further includes a pointed tip.

52. (original) The assembly of claim 51 wherein the pointed tip comprises a truncated cone.

53. (original) The assembly of claim 51 wherein the pointed tip comprises a sectioned portion.

54. (original) The assembly of claim 47 wherein the through channel of the fastener comprises a through bore.

55. (original) The assembly of claim 47 wherein both the first and second members include a longitudinal axis and a through channel along each respective axis.

56. (original) The assembly of claim 55 wherein one end of both the first and second members includes a pointed tip.

57. (original) The assembly of claim 56 wherein the pointed tips point in opposite directions.

58. (original) The assembly of claim 55 wherein the through channels are through bores.

59. (original) The assembly of claim 55 wherein the through channels of the first and second members are arranged to be slidably received by the tissue piercing deployment wire and wherein the connecting member is flexible permitting the first and second members to be in line with each other on the tissue piercing deployment wire.

60. (original) The assembly of claim 59 further comprising a guide tube extending over the deployment wire and the fastener.

61. (original) The assembly of claim 47 wherein the first member, the second member, and the connecting member of the fastener are all formed of plastic material.

62. (original) The assembly of claim 61 wherein the first member, the second member, and the connecting member of the fastener are all formed in one piece.

63. (original) The assembly of claim 47 wherein the first member, the second member, and the connecting member of the fastener comprises separate pieces.

64. (original) The assembly of claim 47 wherein one end of the one of the first and second members of the fastener further includes a dilation tip.

65. (original) The assembly of claim 64 wherein the dilation tip is a pointed tip.

66. (original) The assembly of claim 65 wherein the pointed tip of the fastener is conical.

67. (original) The assembly of claim 47 wherein the through channel of the fastener comprises a through bore.

68. (original) The assembly of claim 47 wherein both the first and second members of the fastener include a longitudinal axis and a through channel along each respective axis.



69. (original) The assembly of claim 68 wherein one end of both the first and second members of the fastener includes a dilation tip.

70. (original) The assembly of claim 69 wherein the dilation tips point in opposite directions.

71. (original) The assembly of claim 47 wherein the connecting member of the fastener is formed of plastic elastic material.

72. (original) The assembly of claim 71 wherein the connecting member of the fastener is formed of one of polyurethane, thermoplastic elastomer, and polypropylene.

73. (original) The assembly of claim 47 wherein the connecting member of the fastener is formed of a plastic, permanently deformable material.

74. (original) The assembly of claim 73 wherein the connecting member is formed of one of polypropylene and polyethylene.

75. (original) The assembly of claim 61 wherein the plastic material includes a color pigment contrasting with body tissue color to enable visualization of the fastener with an endoscope.

76. (original) The assembly of claim 47 wherein the connecting member of the fastener has a vertical dimension and a horizontal dimension transverse to the vertical dimension, and wherein the horizontal dimension is substantially less than the vertical dimension rendering the connecting member readily bendable in a horizontal plane.

77. (original) The assembly of claim 47 wherein at least one of the first and second members of the fastener includes a plurality of longitudinally spaced vertical

slots rendering the at least one of the first and second members flexible in a direction opposite the slots but stiff in a direction of the slots.

78. (original) The assembly of claim 47 wherein the first member, the second member, and the connecting member of the fastener are integrally formed from a same tubular member stock.

79. (original) The assembly of claim 78 wherein both the first and second members of the fastener include a through channel for being slidably received in line on the tissue piercing deployment wire.

80. (original) The assembly of claim 47 wherein the fastener is formed of metal.

81. (original) The assembly of claim 47 wherein the fastener is formed of a shape memory material and wherein the first and second members are self-deployable.

82. (original) The assembly of claim 81 wherein the fastener is formed of Nitinol.

83. (original) The assembly of claim 79 wherein at least one of the first and second members of the fastener is self-deployable while on the tissue piercing deployment wire.

84. (original) The assembly of claim 79 wherein at least one of the first and second members of the fastener is self-deployable upon removal from the tissue piercing deployment wire.

85. (original) The assembly of claim 84 wherein the at least one of the first and second members of the fastener is distal to another one of the first and second members and wherein the another one of the first and second members includes a crimp that provides a controlled resistance to movement on the tissue piercing deployment wire.

86. (original) The assembly of claim 78 wherein the connecting member comprises a strip of the tubular member formed by a pair of longitudinal substantially parallel substantially coextensive cuts within the tubular member and the first and second members are formed by a substantially transverse circumferential cut between the substantially parallel coextensive cuts.

87. (original) The assembly of claim 86 wherein the tubular member has first and second exposed ends and wherein the substantially parallel substantially coextensive cuts begin spaced from the first end and terminate spaced from the second end, and wherein the first and second members are tubular member sections between the circumferential cut and the tubular member first and second ends.

88. (original) The assembly of claim 87 wherein the tubular member includes an elongated notch extending from one of the ends of the tubular member, substantially diametrically opposite and juxtaposed to a portion of the connecting member strip.

89. (original) The assembly of claim 47 wherein the fastener is formed of a shape memory material.

90. (original) The assembly of claim 89 wherein the shape memory material is Nitinol.

91. (original) The assembly of claim 87 wherein both the first and second tubular members are arranged to be slidably received on the deployment wire.

92. (original) The assembly of claim 91 further comprising a guide tube extending over the deployment wire and fastener.

93. (original) The assembly of claim 92 wherein the fastener is formed of a shape memory material.

94. (original) The assembly of claim 93 wherein the shape memory material is Nitinol.

95. (original) The assembly of claim 47 further comprising a guide tube extending over the deployment wire and fastener and wherein the guide tube includes a distal notch permitting a proximal one of the first and second members to deploy before the guide tube proximally clears the proximal member.

96. (original) The assembly of claim 95 wherein the proximal one of the first and second members is deployable while on the deployment wire.

97. (original) The assembly of claim 47 wherein the deployment wire includes a bent tip.

98. (original) The assembly of claim 47 further comprising a plurality of the fasteners slidably received on the deployment wire.

99. (original) A tissue fixation assembly comprising:  
a fastener, and

a pair of hingedly coupled first and second arms for receiving the tissue therebetween, the first arm including a fastener director that directs the fastener into the tissue and the second arm including an opening permitting the fastener to be driven through the tissue while being held between the first and second arms.

100. (original) The assembly of claim 99 wherein the second arm is a frame structure.

101. (original) The assembly of claim 99 further comprising a tissue gripper that grips the tissue and pulls the tissue into and between the first and second arms.

102. (original) The assembly of claim 99 wherein the first arm has a tissue engaging surface and wherein the fastener director includes a channel communicating with the tissue engaging surface through which the fastener passes into the tissue.

103. (original) The assembly of claim 102 wherein the fastener director includes a plurality of the channels to direct a like plurality of fasteners into the tissue.

104. (original) The assembly of claim 102 further comprising a fastener deployment wire extending through the channel and that guides the fastener through the channel and into the tissue.

105. (original) The assembly of claim 104 wherein the fastener comprises a first member, a second member, the first and second members having first and second ends, and a connecting member fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members, the first and second members being substantially parallel to each other and separated by the connecting member when the fastener is deployed, and one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidably received on the fastener deployment wire.

106. (original) A transoral gastroesophageal flap valve restoration device comprising:

- a longitudinal member, a portion of which is arranged for transoral placement into a stomach;

- a fastener; and

- a tissue shaper carried on the longitudinal member that shapes stomach tissue into a shape, the tissue shaper comprising a pair of hingedly coupled first and second arms for receiving the stomach tissue therebetween, the first arm including a fastener director that directs the fastener into the stomach tissue and the second arm including an opening permitting the fastener to be driven through the stomach tissue while being held between the first and second arms.

107. (original) The device of claim 106 wherein the second arm of the tissue shaper is a frame structure.

108. (original) The device of claim 106 wherein the tissue shaper further comprises a tissue gripper that grips the stomach tissue and pulls the stomach tissue into and between the first and second arms.

109. (original) The device of claim 106 wherein the first arm of the tissue shaper has a tissue engaging surface and wherein the fastener director includes a channel communicating with the tissue engaging surface through which the fastener passes into the stomach tissue.

110. (original) The device of claim 109 wherein the fastener director includes a plurality of the channels to direct a like plurality of fasteners into the stomach tissue.

111. (original) The device of claim 109 further comprising a fastener deployment wire extending through the channel and that guides the fastener through the channel and into the stomach tissue.

112. (original) The device of claim 111 wherein the fastener comprises a first member, a second member, the first and second members having first and second ends, and a connecting member fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members, the first and second members being substantially parallel to each other and separated by the connecting member when the fastener is deployed, and one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidably received on the fastener deployment wire.

113. (new) A tissue fixation assembly comprising:  
a fastener;

a pair of hingedly coupled first and second arms for receiving the tissue therebetween, the first arm including a fastener director that directs the fastener into the tissue and the second arm including an opening permitting the fastener to be driven through the tissue while being held between the first and second arms; and

a tissue gripper including a helical coil that grips the tissue and pulls the tissue into and between the first and second arms,

wherein the fastener comprises a first member, a second member, the first and second members having first and second ends, and a connecting member fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members, the first and second members being substantially parallel to each other and separated by the connecting member when the fastener is deployed, and one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidably received on a fastener deployment wire.

114. (new) A transoral gastroesophageal flap valve restoration device comprising:

a longitudinal member, a portion of which is arranged for transoral placement into a stomach;

a fastener;

a tissue shaper carried on the longitudinal member that shapes stomach tissue into a shape, the tissue shaper comprising a pair of hingedly coupled first and second arms for receiving the stomach tissue therebetween, the first arm including a fastener director that directs the fastener into the stomach tissue and the second arm including an opening permitting the fastener to be driven through the stomach tissue while being held between the first and second arms; and

a tissue gripper including a helical coil that grips the stomach tissue and pulls the stomach tissue into and between the first and second arms,

wherein the fastener comprises a first member, a second member, the first and second members having first and second ends, and a connecting member fixed to each of the first and second members intermediate the first and second ends and extending

between the first and second members, the first and second members being substantially parallel to each other and separated by the connecting member when the fastener is deployed, and one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidingly received on a fastener deployment wire.